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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,926	12/30/2004	Jean-Luc Carrez	MART0850US	3170
24235 7590 02/26/2008 LEVINE & MANDELBAUM 444 MADISON AVENUE 35TH FLOOR NEW YORK, NY 10022			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 02/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/519,926

**Applicant(s)**

CARREZ ET AL.

**Examiner**

LAURA A. BOUCHELLE

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/7/07 has been entered.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities: Puncture is misspelled in line 2 of the claim. Appropriate correction is required.
3. Claim 3 is objected to because of the following informalities: Claim 3 depends from claims 1 or 2, however claim 2 has been cancelled. Appropriate correction is required.
- 4.

### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 1, 3, 4-6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honebrink et al (US 6589262) in view of Falvai et al (US 5782807). Honebrink discloses a catheter introducing device comprising a needle 120 having a fixed hub 126, a cannula 140 having a longitudinal slit 222 for slidably receiving a catheter. The hub of the cannula has side teeth 162 that cooperate with retaining tabs 134 on the front of the hub of the needle. The cooperating locks are releasable by relative rotation of the two hubs.

7. Claim 1 differs from Honebrink in calling for the hub and the shaft to be made of different synthetic resins. Honebrink is silent as to the materials used to form the device. Falvai teaches an insertion device formed of a synthetic resin. The shaft and the hub may be formed of different materials having different flexibilities (Col. 7, lines 22-26, 34-37). It is well known in the art to use synthetic resins to form medical devices because of the biocompatibility, durability, low cost and ease of manufacture. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Honebrink to be formed of a synthetic resin as taught by Falvai.

8. Claim 3 differs from Honebrink in calling for the shaft to be glued into the slit in the hub. This limitation is considered to be product by process claims. These claims are not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honebrink in view of Falvai in further view of Thompson et al (US 3827434).

10. Honebrink does not explicitly disclose the structure of the catheter. Thompson teaches a catheter insertion device comprising a catheter having a fixed hub 36 that allows the device to be releasably locked to the insertion member. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Honebrink to include a catheter with a hub as taught by Thompson so that the catheter can be releasably locked to the insertion member.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honebrink in view of Falvai in further view of Center (US 3682173).

12. Claim 8 differs from Honebrink in calling for a pack containing the catheter, needle, and cannula. Center teaches a catheter insertion device contained in a package so that the entire device can be sterilized and remains sterile until it is ready to be used. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Honebrink so that the device is contained in a package as taught by Center so that the device remains sterile before use.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honebrink in view of Falvai in further view of Melsky (US 4973319).

14. Honebrink is silent as to the method of manufacturing the device as described in claim 9. Melsky teaches a method of manufacturing a slit valve catheter wherein one member is glued into another member and then the first member is slit by any appropriate means (Col.3, lines 49-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to glue the cannula of Honebrink into the slit hub and then slit the cannula as taught by Melsky.

***Response to Arguments***

15. Applicant's arguments filed 12/7/07 have been fully considered but they are not persuasive.

16. Applicant argues that the sheath of Honebrink does not have a slit for removing it from a catheter. The examiner disagrees with this argument for a variety of reasons. First, Honebrink discloses that the sheath is separably or splittable by means of an external score. A score is, by definition, a notch or scratch. A slit is a narrow cut or opening. The examiner interprets an external score to be a slit in the external portion of the sheath. Second, if applicant does not accept the examiner's interpretation of the language, as the sheath is being split, the score lines in the sheath become slits. Finally, the examiner points applicant to col. 4, lines 37-41 wherein Honebrink discloses that the sheath may be separated by any technique which is well known in the art, as the examiner asserts a split is.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle  
Examiner  
Art Unit 3763